

Docket No.: 0230-0245PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hidemi KURIHARA et al.

Application No.: 10/571,069

Confirmation No.: 2459

Filed: December 7, 2006

Art Unit: 1649

For: THERAPEUTIC AGENT AND THERAPEUTIC
METHOD FOR PERIODONTAL DISEASES
AND PULPAL DISEASES

Examiner: C. M. Borgeest

DECLARATION SUBMITTED UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 5, 2010

Sir:

I, Dr. Hidemi KURIHARA of the Department of Periodontal Medicine, Division of
Fronteier Medical Science, Graduate School of Biomedical Sciences, Hiroshima University,
Japan, do hereby declare the following:

I have attached a copy of my curriculum vitae to this Declaration.

I am Professor and chair of Department of Periodontal Medicine and have worked in this
field for 30 years.

I am one of the inventors of the above referenced patent application.

I am familiar with the patent application, as well as the development, usages and
properties of polymer compounds.

I have read and understand the subject matter of the Office Action of April 5, 2010.

The following comments are offered in support of the patentability of the instant invention.

The Examiner states "Applicants present only argument, without any evidence that one of skill in the art would understand periodontal tissue regeneration as excluding ankylosis." To assist the Examiner in properly understanding what one of skill in the art would have understood at the time that this application was filed, I offer the following remarks.

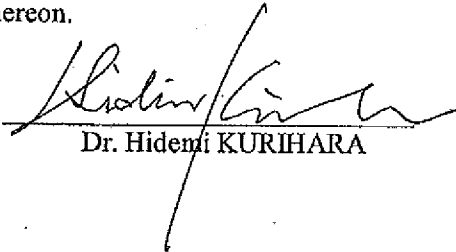
1. Normal Periodontal Tissue – Periodontal tissue was thought to consist of the supporting tissues of the tooth (gingival, periodontal ligament, cementum and alveolar bone). The cementum is important because it provides the site of anchorage of the periodontal ligament fibers on the tooth. It is a mineralized tissue, covering the entire root surface of the tooth and firmly bound to the underlying dentine. See Section One and pages 36-39 Clinical Periodontology 8th edition (1996) Fermin A. Carranza et al., eds., W.B. Saunders Company, Philadelphia.
2. Destruction of Periodontal Tissue – The destruction of periodontal tissue occurs when interaction between bacteria in dental plaque and host defence reactions becomes unstable. The histological features include: (1) marked apical migration and lateral extension of junctional epithelium, with areas of ulceration; (2) loss of connective tissue attachment, resulting in true periodontal pocket formation; (3) loss of alveolar bone; (4) extensive chronic inflammatory infiltrate in connective tissue. See pages 32-39 9 of Pathology of Periodontal Disease (1992) David M. Williams et al. (eds), Oxford University Press, USA.
3. Ankylosis – Fusion of the cementum and alveolar bone with obliteration of the periodontal ligament is termed *ankylosis*. Ankylosis results in resorption of the root and its gradual replacement by bone tissue. See pages 40-41 Clinical Periodontology 8th edition (1996) Fermin A. Carranza et al., eds., W.B. Saunders Company, Philadelphia.

4. Complete Periodontal Tissue Regeneration - The complete periodontal tissue regeneration requires the attachment of periodontal ligament cells and fibers to the previously denuded root surface with new cementum formation, the formation of a functionally orientated fiber network emanating from the root, and the coronal regrowth of the alveolar bone. However, the current periodontal therapy almost never achieves the new attachment formation or bone regeneration. See pages 32-39 and 138-139 of Pathology of Periodontal Disease (1992) David M. Williams et al. (eds), Oxford University Press, USA. See pages 138-139 of Pathology of Periodontal Disease (1992) David M. Williams et al. (eds), Oxford University Press, USA.

The undersigned hereby declares that all statements made herein based upon knowledge are true, and that all statements made based upon information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED:

Aug. 5, 2010



Dr. Hidenori KURIHARA